



**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2011-0604; FRL-9342-5]**

**2-Ethyl-1-hexanol; Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation amends an exemption from the requirement of a tolerance for residues of 2-ethyl-1-hexanol (CAS no. 104-76-7) to increase the maximum use level for residues from 2.5% to 10% in final pesticide formulations, when used as an inert ingredient as a cosolvent, defoamer, solvent in pesticide formulations, inert ingredients used pre- and post-harvest, and inert ingredients applied to animals. Cognis submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to the existing exemption for 2-ethyl-1-hexanol.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2011-0604. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Janet Whitehurst, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6129; e-mail address: [whitehurst.janet@epa.gov](mailto:whitehurst.janet@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0604 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0604, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## **II. Petition for Exemption**

In the **Federal Register** of September 7, 2011 (76 FR 55329) (FRL-8886-7), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 1E7893) by Cognis Corporation, c/o Lewis & Harrison LLC, 122 C St., NW, Suite 740, Washington DC 20001. The petition requested that 40 CFR 180.910 and 180.930 be amended by modifying an exemption from the requirement of a tolerance for residues of 2-ethyl-1-hexanol (CAS Reg. No. 104-76-7) to increase the maximum use level from 2.5% to 20% in final pesticide formulations when used as an inert ingredient as a cosolvent, defoamer, solvent in

pesticide formulations applied to agricultural growing crops or to raw agricultural commodities after harvest and direct application to animals. That notice referenced a summary of the petition prepared by Cognis Corporation, c/o Lewis & Harrison LLC, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has increased the maximum use limit for 2-ethyl-1-hexanol under 40 CFR 180.910 and 180.930 to 10% and not 20% as requested by the petitioner due to aggregate risk concern. This limitation is based on the Agency's risk assessment which can be found at <http://www.regulations.gov> in the document "Decision Document for Petition Number 1E7893:2-Ethylhexanol; Human Health Risk Assessment and Ecological Effects Assessment for Proposed Exemption from Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations," in docket ID number EPA-HQ-OPP-2011-0604.

### **III. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 2-ethyl-1-hexanol including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 2-ethyl-1-hexanol follows.

*A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by 2-ethyl-1-hexanol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit. The available toxicity studies for 2-ethyl-1-hexanol are summarized in detail in the Decision Document for Petition Number 1E7893: "2-Ethylhexanol; Human Health Risk Assessment and Ecological Effects Assessment for Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations."

The Agency has determined that 2-ethyl-1-hexanol is of low acute toxicity by the oral and dermal routes. Studies in rats and mice have LD<sub>50</sub>s ranging from 2,000 to 6,400 milligrams/kilogram (mg/kg) of body weight. 2-Ethyl-1-hexanol is moderately irritating to the skin and severely irritating to the eye. Eleven subacute and subchronic studies have been performed with 2-ethyl-1-hexanol.

All the studies show that repeated exposure to 2-ethyl-1-hexanol has low potential for toxicity. The major target organ for 2-ethyl-1-hexanol is the liver with peroxisome proliferation as the major hepatic endpoint. The lowest NOAEL was observed in rats at 100 mg/kg/day based on liver weights and liver peroxisomes at the LOAEL of 320 mg/kg/day. No neurotoxic effects, even at high doses, were observed in the subchronic or chronic studies, so there is no reason to assume 2-ethyl-1-hexanol has neurotoxic potential.

Numerous genotoxicity studies have been conducted with 2-ethyl-1-hexanol, including five Ames tests, an *in vitro* cell transformation assay, an 8-azaguanine resistance assay, a mouse micronucleus test, a mouse lymphoma assay, a Rec-assay, a CHO mutation assay, an unscheduled DNA synthesis assay, an *in vivo* dominant lethal assay and an *in vivo* chromosomal aberration assay. The results of all *in vitro* assays except the 8-azaguanine resistance assay were negative and all *in vivo* studies were negative as well. The genotoxicity data clearly indicate that 2-ethyl-1-hexanol is not mutagenic.

Carcinogenicity studies in both rats and mice were conducted. In the mouse study, male and female mice were gavaged with 2-ethyl-1-hexanol at doses of 0, 50, 200 or 750 mg/kg/day for 18 months. No substance-related changes were seen at 50 or 200 mg/kg/day. At 750 mg/kg/day, reduced body weight gain related to decreased food consumption and increased mortality was noted. Treatment-related hematological changes were seen, and slight but not statistically significant increases were noted in focal hyperplasia of the epithelium of the forestomach. No statistically significant increases in tumor incidence were noted in mice. In the rat study, male and female rats were gavaged five days/week for 24 months at 0, 50, 150 or 500 mg/kg/day. Dose-related reduced body weight gain was noted at 150 mg/kg/day and higher. Clinical findings included poor general condition, labored breathing, and piloerection. Increased



mortality occurred in females at 500 mg/kg/day. No increase in tumor incidence was noted. Based on the results of the rat and mice studies and lack of mutagenicity concerns, it can be reasonably concluded that 2-ethyl-1-hexanol is not likely to be carcinogenic.

Developmental toxicity studies have been performed with 2-ethyl-1-hexanol; and a reproductive study has been performed using diethylhexyl adipate (DEHA) that readily metabolizes to 2-ethyl-1-hexanol in mammals. EPA concluded that none of the studies showed any developmental or reproductive toxicity associated with 2-ethyl-1-hexanol, even at high dose levels.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

Several subchronic, chronic/carcinogenicity studies are available for 2-ethyl-1-hexanol. No endpoint of concern for acute exposure was identified in the available database. The NOAEL, from the carcinogenicity study in rat was 50 mg/kg/day based on dose-related reduced body weights at the LOAEL of 450 mg/kg/day. The chronic RfD is 0.5 mg/kg/day using a hundredfold uncertainty factor (10X intraspecies and 10X interspecies variation). The population adjusted dose is equal to chronic RfD (0.5 mg/kg/day) since the FQPA factor is reduced from 10X to 1X. This endpoint of concern was used for all exposure durations in order to be conservative in the risk assessment.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 2-ethyl-1-hexanol EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 2-ethyl-1-hexanol in food as follows: The I-Dietary Exposure Evaluation Model (DEEM) is a highly conservative model with the assumption that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity.

Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops (every food eaten by a person each day has tolerance-level residues).

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for 2-ethyl-1-hexanol, a conservative drinking water concentration value of 100 parts per billion

(ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

There are no current residential uses known to the Agency and thus no residential exposures are expected. Therefore, a residential exposure assessment was not conducted.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCFA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found 2-ethyl-1-hexanol to share a common mechanism of toxicity with any other substances, and 2-ethyl-1-hexanol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 2-ethyl-1-hexanol does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCFA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects

to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There are several developmental toxicity studies available in mice and rats by the gavage route. One developmental toxicity study in rats via inhalation and a dermal developmental toxicity study in mice are also available. In one developmental toxicity study in mice via oral route, no developmental toxicity was observed at the highest dose of 1,525 mg/kg/day. In a separate developmental toxicity study in mice via oral route, no developmental effects were observed at doses up to 135 mg/kg/day (the highest dose tested, HDT). In a rat developmental toxicity study via oral routes, the NOAEL for developmental and maternal toxicity was 800 mg/kg/day based on hydronephrosis and tail abnormalities seen at the LOAEL of 1,600 mg/kg/day above the limit dose of 1,000 mg/kg/day. No developmental toxicity was seen in rats (inhalation) and mice (dermal) at doses up to 850 mg/m<sup>3</sup> and 2,520 mg/kg/day, respectively. The available data on developmental toxicity studies with 2-ethyl-1-hexanol clearly indicate no evidence of increased susceptibility for infants and children. No two generation reproduction study is available in the database for 2-ethyl-1-hexanol, however, no effects on sperm and other reproductive parameters were observed in rats at doses up to 1,080 mg/kg/day when fed on diets containing diethylhexyl adipate (DEHA). In mammals, DEHA is readily metabolized to 2-ethyl-1-hexanol. None of the studies showed any

developmental or reproductive toxicity associated with 2-ethyl-1-hexanol, even at high dose levels.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for 2-ethyl-1-hexanol includes several subchronic, chronic/carcinogenicity studies, mutagenicity studies, metabolism studies, and developmental studies. No two generation reproduction study is available in the database for 2-ethylhexanol, however, no effects on sperm and other reproductive parameters were observed in rats at doses up to 1,080 mg/kg/day when fed on diets containing diethylhexyl adipate (DEHA). In mammals, DEHA is readily metabolized to 2-ethylhexanol.

ii. There is no indication that 2-ethyl-1-hexanol is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity. No neurotoxicity studies are available in the database, however, no clinical signs of neurotoxicity were observed in the available subchronic and chronic studies. Therefore, the developmental neurotoxicity study is not necessary at this time.

iii. No immunotoxicity study is available, however, there were no effects on the thymus or spleen indicated in the available database. Therefore, an immunotoxicity study is not required.

iv. There is no evidence that 2-ethyl-1-hexanol results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in the 2-generation reproduction study with a surrogate chemical.

v. There are no residual uncertainties identified in the exposure databases. The food and drinking water assessment is not likely to underestimate exposure to any subpopulation, including those comprised of infants and children. The food exposure assessments are considered to be highly conservative as they are based on the use of the highest tolerance level from the surrogate pesticides for every food and 100% crop treated is assumed for all crops. EPA also made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to 2-ethyl-1-hexanol in drinking water. These assessments will not underestimate the exposure and risks posed by 2-ethyl-1-hexanol.

*E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, 2-ethyl-1-hexanol is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to 2-ethyl-1-hexanol from food and water will utilize 7.7% of the cPAD for U.S. population and 25% for children age 1 to 2 years, the

population group receiving the greatest exposure. There are no residential uses for 2-ethyl-1-hexanol. Based on the explanation in this unit, regarding residential use patterns, chronic residential exposure to residues of 2-ethyl-1-hexanol is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, 2-ethyl-1-hexanol is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for 2-ethyl-1-hexanol.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, 2-ethyl-1-hexanol is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is

necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for 2-ethyl-1-hexanol.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies and lack of mutagenicity concerns, 2-ethyl-1-hexanol is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to 2-ethyl-1-hexanol residues.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of 2-ethyl-1-hexanol in or on any food commodities. EPA is establishing a limitation on the amount of 2-ethyl-1-hexanol that may be used in pesticide formulations. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. EPA will not register any pesticide for sale or distribution that contains greater than 10% of 2-ethyl-1-hexanol in food use pesticide formulations.

### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCa section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture



Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for 2-ethyl-1-hexanol.

## **VI. Conclusions**

Therefore, the exemptions from the requirement of a tolerance for 2-ethyl-1-hexanol (CAS Reg. No. 104-76-7) at 40 CFR 180.910 and 180.930 are amended to increase the maximum use level from 2.5% to 10% in final pesticide formulations.

## **VII. Statutory and Executive Order Reviews**

This final rule amends an exemption from the requirement for a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “*Regulatory Planning and Review*” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “*Protection of Children from Environmental Health Risks and Safety Risks*” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “*Federal Actions to*

*Address Environmental Justice in Minority Populations and Low-Income Populations*” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “*Federalism*” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “*Consultation and Coordination with Indian Tribal Governments*” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

### **VIII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 27, 2012.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In §180.910 revise the entry for 2-Ethyl-1-hexanol to read as follows:

**§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
<p style="text-align: center;">*      *</p> <p>2-Ethyl-1-hexanol (CAS Reg. No. 104-76-7)</p> <p style="text-align: center;">*      *</p>	<p style="text-align: center;">*      *</p> <p>Not more than 10% of pesticide</p> <p style="text-align: center;">*      *</p>	<p style="text-align: center;">*      *</p> <p>Solvent, adjuvant of surfactants</p> <p style="text-align: center;">*      *</p>

3. In § 180.930 revise the entry for 2-Ethyl-1-hexanol to read as follows:

**§ 180.930 Inert Ingredients applied to animals; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
<p style="text-align: center;">*      *</p> <p>2-Ethyl-1-hexanol (CAS Reg. No. 104-76-7)</p> <p style="text-align: center;">*      *</p>	<p style="text-align: center;">*      *</p> <p>Not more than 10% of pesticide</p> <p style="text-align: center;">*      *</p>	<p style="text-align: center;">*      *</p> <p>Solvent adjuvant of surfactants</p> <p style="text-align: center;">*      *</p>